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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,473	06/23/2003	Thomas J. Boyd	IR 7348-01	7614

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EXAMINER

KRASS, FREDERICK F

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 09/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/601,473

Applicant(s)

BOYD ET AL.

Examiner

Frederick F. Krass

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
- Paper No(s)/Mail Date A & B.

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Indefiniteness Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) The term "rapidly" in claim 1 is a relative term which renders the claim indefinite. The term "rapidly" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Since the term is not necessary to an understanding of the claimed subject matter, the examiner recommends deleting it.

2) Claim 1 is incomplete insofar as the variable "n" in the structural formula is not defined.

3) Claim 7, first line, "the arginine derivative compound" lacks antecedent basis; this is apparently the result of an oversight on Applicant's part, insofar as claim 7 should depend from claim 6, not claim 1. Correction is required.

Obviousness Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious

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at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1) Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu et al (USP 6,419,903) in view of Saito (USP 3,825,560).

The primary reference discloses orally consumable films which dissolve in the oral cavity to release breath fresheners. The preferred film-forming material is hydroxymethylpropyl cellulose (col. 2, last paragraph), which is present in an amount 10 to about 60 percent by weight of the film (col. 3, lines 8-11). Breath fresheners include zinc gluconate (col. 4, lines 40-49).

The primary reference differs from the instant claims insofar as it is silent regarding the incorporation of an ester salt having the structural formula set forth in claim 1, i.e., an arginine ester salt having a long chain alkyl substituent. The primary reference does teach incorporating additional ingredients, however, e.g., other antimicrobial agents; surfactants; etc. (col. 2, lines 21-27).

The secondary reference discloses compositions containing the instantly claimed arginine ester salts having a long chain alkyl substituent as antimicrobial agents (see the passage bridging col. 2, lines

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68 to col. 4, line 31). Moreover, the secondary reference clearly teaches that such esters are ideal for use in disinfecting the oral cavity because they adhere to the oral mucosa, while providing activity against common oral pathogens associated with caries, plaque and gum disease (all underlying causes of bad breath). See col. 7, lines 43-50. Note also that the prior art further teaches that arginine esters are also desirable for use in oral care compositions because of their surfactant properties (col. 8, lines 2-8). See also working examples 12 and 13 at col. 11, wherein dentifrice compositions are specifically prepared; the use of 3 percent by weight arginine ester in those examples makes clear that only a small amount (falling squarely within the instantly preferred range of instant claim 5) is necessary to obtain the desired activity. The secondary reference differs from the instant claims insofar as it does not specifically disclose orally consumable films (the specific examples of oral care compositions it provides are "conventional" dentifrices such as toothpastes).

It would have been obvious to have incorporated a long chain alkyl arginine ester salt into the orally consumable films of the primary reference, motivated by the desire to simultaneously provide the extended antimicrobial activity and surfactant properties expected therefor as taught by the secondary reference.

Regarding instant claim 7, the secondary reference differs from the instant claims insofar as it does not specifically disclosed (by name or specific formula) the hydrochloride salt of ethyl lauroyl arginine ("LAE"). That compound is, however, clearly within the scope of the generic formula provided at the top of col. 3. And, moreover, the hydrochloride salt of methyl lauroyl arginine, LAE's methyl homologue, is specifically disclosed, tested, and included in various working example formulations: see for example col. 4, lines 20 and 21; the third compound of Table I at col. 4; col. 7, line 5; and col. 8, line 16.

It is well-settled that when chemical compounds have "very close" structural similarities and similar utilities, without more a prima facie case may be made. See In re Deuel, 51 F.3d 1552, 1559 (Fed. Cir. 1995). The necessary motivation to make the claimed compound, and thus the prima facie case of obviousness, arises from the reasonable expectation that compounds similar in structure will have similar

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properties. In re Gyurik, 596 F.2d 1012, 1018 (1979). The classic example of "very close" structural similarity is that of adjacent homologues.

Accordingly, it would have been obvious to have used LAE as an arginine ester salt of the secondary reference, since it and methyl lauroyl arginine have "very close" structural similarities, consonant with the reasoning of the precedent cited supra.

2) Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Xu et al (USP 6,419,903) in view of Saito (USP 3,825,560), the combination being taken further in view of Beltran et al (WO 03/043593).

The primary and secondary references, and the rationale for combining their teachings, are discussed in subsection "1)" supra. The compositions suggested by their combined teachings differ from the instant claim insofar as the hydrochloride salt of ethyl lauroyl arginine ("LAE") is not explicitly disclosed, although same is clearly within the scope of the general structural formulae set forth at the passage bridging col. 2, lines 68 to col. 4, line 31 of the secondary reference.

The tertiary reference teaches that LAE has exceptional antimicrobial activity when used in oral care compositions. See p. 2, lines 11-14 and p. 3, lines 20-27. It differs from the instant claims insofar as it does not specifically disclose orally consumable films (the specific examples of oral care compositions it provides are "conventional" dentifrices such as toothpastes).

It would have been obvious to have used LAE as an arginine ester of the secondary reference, motivated by the desire to impart the exceptional antimicrobial activity expected for same from the teachings of the tertiary reference.

3) Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu et al (USP 6,419,903) in view of Beltran et al (WO 03/043593).

The primary reference discloses orally consumable films which dissolve in the oral cavity to release breath fresheners. The preferred film-forming material is hydroxymethylpropyl cellulose (col. 2,

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last paragraph), which is present in an amount 10 to about 60 percent by weight of the film (col. 3, lines 8-11). Breath fresheners include zinc gluconate (col. 4, lines 40-49).

The primary reference differs from the instant claims insofar as it is silent regarding the incorporation of an ester salt having the structural formula set forth in claim 1, i.e., an arginine ester salt having a long chain alkyl substituent. The primary reference does teach incorporating additional ingredients, however, e.g., other antimicrobial agents (col. 2, lines 21-27).

The secondary reference teaches that LAE has exceptional antimicrobial activity when used in oral care compositions. See p. 2, lines 11-14 and p. 3, lines 20-27. It differs from the instant claims insofar as it does not specifically disclose orally consumable films (the specific examples of oral care compositions it provides are "conventional" dentifrices such as toothpastes).

It would have been obvious to have used LAE as an antimicrobial agent in the primary reference orally consumable films, motivated by the desire to impart the exceptional antimicrobial activity expected for same from the teachings of the secondary reference.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is 9:30AM – 6:00PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

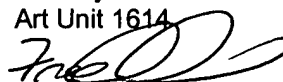
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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC)
at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
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A handwritten signature in black ink, appearing to read 'Frederick Krass', written over the printed name.